

The Safe Hands of ICP-MS

Originally Published: 29-Apr-2021 by [The Analytical Scientist](#)



Anna Cousens, Global Analytical BDM at Almac Sciences, discusses ICP-MS analysis and the importance of getting it right in drug development

Almac Sciences – part of the Almac Group – provides integrated services from development to commercial scale for API and finished products and employs over 170 highly skilled analysts working in GMP/ GLP environments across the UK, Europe, and US. We spoke to Anna Cousens, Global Analytical Business Development Manager, about inductively coupled plasma MS (ICP-MS) and its importance in drug development.

What is ICP-MS and why is it important to drug development?

ICP-MS is a spectroscopic analytical technique with applications in the detection of metals in drugs. It is one of many different analytical techniques in use in the industry to ensure that all drugs on the market are safe to use, manufactured to a high standard, and free from impurities. ICP-MS is a relatively new technology that came into mainstream use three years ago, when new US Pharmacopoeia regulations were implemented regarding limits on heavy metals in pharmaceutical products.

The US Pharmacopoeia is considered the gold standard of pharmaceutical testing. It covers a wide range of analysis, but chapters <232> Elemental Impurities – Limits and <233> Elemental Impurities – Procedures specify limits and analytical procedures for elemental impurities in drug products. These new chapters came into force on January 1, 2018, and prompted updates to ICP-MS analysis in the industry.

How did the updated regulations drive changes in the market?

These regulations impacted how CDMOs and pharma companies performed their analyses. In the last three years, there has been significant activity in this space as manufacturers sought to comply with the new regulations. Because any pharmaceutical product sold in the US needed to be in compliance, the changes were felt across all drug delivery platforms from tablets and capsules to vials, injectables, and even devices. In addition, the regulations had repercussions for suppliers because the final product manufacturers performed risk assessments to see where elemental impurities could originate. This led to a significant increase in the number of requests to API, raw material, and excipient suppliers and manufacturers for information about their procedures.

Essentially, the entire industry had to update their testing regimens to include the new ICP-MS standards. Some companies with very low risk of elemental impurities performed a risk assessment that limited the amount of testing required, whereas others had to completely rethink their approach and develop and validate new ICP-MS methods for their entire product portfolio. With increased demand in testing, equipment

How did Almac react?

Almac invested heavily in both equipment and staff, employing team leaders with experience in method development and validation, purchasing state-of-the-art equipment, and qualifying that equipment for GMP use. This included an Agilent 7900 and a Thermo iCAP RQ.

Over the last five years, Almac has developed a wealth of experience, performing 57 validations (phase I to commercial release), offering QC support for more than 30 APIs, and analyzing approximately 60 different test articles – including drug substance/API, excipient/drug product, and raw materials.

We have robust methods in place to support our existing clients – and new clients can also leverage our library of methods.

What is next in this space?

The pharma world is constantly evolving. Even now, new guidance is being issued on nitrosamines, which – although not as widely applicable as the heavy metals limits – will be the next big analytical challenge.

With its 20 years of experience in LC-MS, Almac is already working to adapt to these new changes and has methods in place to support clients in this area. LC-MS equipment is managed by Almac's spectroscopy team, a 30-strong group of employees who manage an extensive range of equipment (including 2D LC-MS/MS equipment, GC-MS, and NMR) that is fully GMP-compliant. The team has extensive knowledge of not only the equipment and our library methods, but also structural interpretation and data processing to ensure the correct experiments are run for each project. Despite the ever-changing pharma landscape, our team has the experience and knowledge to help our clients navigate key drug development challenges.

Contact us:

Global HQ

+44 (0) 28 3833 2200

US HQ

+1 (215) 660 8500

Ireland

+353 90 646 0200